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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/400,492	09/21/1999	KENNETH RHODES	MNI-069CP	3470

959 7590 05/20/2003

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28 STATE STREET  
BOSTON, MA 02109

EXAMINER
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MURPHY, JOSEPH F

ART UNIT	PAPER NUMBER
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1646

24

DATE MAILED: 05/20/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/400,492

Applicant(s)

RHODES ET AL.

Examiner

Joseph F Murphy

Art Unit

1646

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 28 February 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-3, 11, 12, 15-19 and 24 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) 1-3, 11-12, 15-19, 24-25 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

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## **DETAILED ACTION**

### ***Formal Matters***

Claims 3, 19 and 25 were amended in Paper No. 23, 2/28/2003. Claims 1-3, 11-12, 15-19, 24 are pending and under consideration.

### ***Response to Amendment***

The rejection of claims 1-3, 11-12, 15-19, 24-25 under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of identifying a compound suitable for treatment wherein the PCIP is 9q, does not reasonably provide enablement for a method of identifying a compound suitable for treatment wherein the polypeptide is a fragment of PCIP 9q, has been obviated by Applicant's amendment, and is thus withdrawn.

### ***Claim Rejections - 35 USC § 112 first paragraph***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-3, 12, 16-19, 24-25 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method for identifying a compound which binds to PCIP 9q, and thus modulates Kv4.2, does not reasonably provide enablement for a method for identifying a compound which is suitable for treating any and all cardiovascular disorders. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

The rejected claims are drawn to a method for identifying a compound which is suitable for treating a cardiovascular disorder. The Merck Manual sets forth that the term cardiovascular

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disease encompasses a broad range of diseases, including, *inter alia*, arterial hypertension, orthostatic hypertension, arteriosclerosis, coronary artery disease, heart failure, shock and arrhythmias (see the Merck manual, pages 1599-1601). While the Specification demonstrates that PCIP 9q can modulate Kv4.2 currents (Specification page 50, Table 1), and thus can modulate Ito and long QT syndrome, the diseases encompassed by the term cardiovascular disorder have many different etiologies, and some for which the etiology is unknown (compare, e.g. arterial hypertension see page 1630, column 1 and arrhythmias page 1711, column 2). It can be seen from the Merck Manual that while the etiology of arterial hypertension is unknown, the etiology of bradyarrhythmias arise through abnormalities of automatic behavior or conduction through the AV node, while tachyarrhythmias often arise through reentry phenomena. Additionally, the Merck Manual teaches that heart failure, which includes the disorder congestive heart failure as set forth in claim 16, also has many possible causes including, *inter alia*, coronary artery disease, hypertension, and cardiomyopathy with congenital defects, as well as mitral stenosis, primary pulmonary hypertension and multiple pulmonary emboli (see page 1684, column 1). Thus the art teaches that there are many and varied etiologies of cardiovascular diseases, including congestive heart failure, and indeed, some etiologies are unknown. Thus the art does not recognize the nexus between a polypeptide, such as PCIP 9q, which can modulate Kv4.2 currents, and any and all cardiovascular disorders, given the many and varied etiologies of the disorders. It would require one of skill in the art to determine the nexus between the disclosed PCIP 9q and all other cardiovascular diseases, since the claims as written encompass identification of compounds which can treat any and all cardiovascular diseases, while the specification only demonstrates that PCIP 9q can bind and modulate Kv4.2 currents. This would

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require undue experimentation on the part of the skilled artisan, since it would require determining the cause of all cardiovascular diseases, and the correlation between the action of PCIP 9q and all cardiovascular diseases.

The claims encompass a method of identifying a compound which binds to PCIP 9q and thus identifying a compound which is suitable for treating a cardiovascular disorder. However, in order for the identified compound to be effective in treating a disorder associated with an abnormal Ito, or treating long QT syndrome, the method should be drawn to identifying a compound which binds PCIP 9q and thereby modulates the activity of Kv4.2. The identification of compounds which only bind but do not modulate would not identify compounds suitable for treating a disorder associated with an abnormal Ito, or treating long QT syndrome.

***Claim Rejections - 35 USC § 112 second paragraph***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 3, 17, 19 and 24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 17, 19 and 24 are vague and indefinite because while claims 17 and 19 recite that an EF domain consists of residues 68-252 of human 9Q, claim 24 sets forth ca. 32 short regions in the polypeptide which are defined as EF domains. It is not clear whether the EF domain is the long domain set forth in claim 17 and 19, or only the short regions as set forth in claim 24.

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Claim 24 is rejected because it does not properly further limit claims 17 and 19. Claim 24 recites many short peptides which the EF domain may be chosen from, thus defining a much larger genus of polypeptides which may be used in the method. Claim 24 is thus broader than either claim 17 or 19, and does not properly further limit claims 17 and 19.

Claims 3 and 19 are vague and indefinite in the recitation of the term "interaction". It is not clear whether this term limits the method to finding a candidate compound which will modulate the binding of PCIP 9q to the K channel, or whether the method is directed to finding a candidate compound which will modulate some other functions that the proteins may have. The metes and bounds of the claims cannot be determined. Claims 11, 12, 15, 16, 24 are rejected insofar as they depend on the recitation on claim 3 and 19 of "interaction"

### ***Conclusion***

Claims 1-3, 11, 12, 15-19, 24-25 are rejected.


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***Advisory Information***

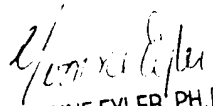
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph F. Murphy whose telephone number is 703-305-7245. The examiner can normally be reached on M-F 7:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached on 703-308-6564. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-308-0294 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.



Joseph F. Murphy, Ph. D.  
Patent Examiner  
Art Unit 1646  
May 14, 2003



YVONNE EYLER, PH.D.  
SUPERVISORY PATENT EXAMINER  
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